

Title 18. State Board of Equalization

NOTICE IS HEREBY GIVEN

The State Board of Equalization (Board), pursuant to the authority vested in it by section 15606, subdivision (a), of the Government Code, proposes to amend Regulation 1591, *Medicines and Medical Devices*, in Title 18, Division 2, Chapter 4, Articles 19 and 20 of the California Code of Regulations, relating to regulatory changes to clarify that all “permanently implanted articles” include the implant’s interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of “medicines.”

“Permanently implanted articles” include the implant’s interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of “medicines.”

A public hearing on the proposed regulations will be held in Room 121, 450 N Street, Sacramento, at 9:30 a.m., or as soon thereafter as the matter may be heard, on Tuesday, February 3, 2009. At the hearing, any person interested may present statements or arguments orally or in writing relevant to the proposed regulatory action. The Board will consider written statements or arguments if received by February 3, 2009.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Revenue and Taxation Code (RTC) section 6369, interpreted and implemented by Regulation 1591, provides that sales of medicines furnished for the treatment of a human being are exempt from sales or use tax if they are sold or furnished under certain conditions, as described in subdivisions (a)(1) through (a)(6) of that section. The term “medicines” is defined by RTC section 6369, subdivision (c), in part, to mean and include “bone screws, bone pins, pacemakers, and other articles, other than dentures, permanently implanted in the human body to assist the functioning of any natural organ, artery, vein, or limb and which remain or dissolve in the body.”

Regulation 1591, subdivision (b)(2), provides in part and with emphasis added:

“Articles permanently implanted in the human body to assist the functioning of, as distinguished from replacing all or any part of, any natural organ, artery, vein or limb and which remain or dissolve in the body qualify as medicines....”

“Permanently implanted articles include, but are not limited to, permanently implanted artificial sphincters; bone screws and bone pins, dental implant systems including dental bone screws and abutments; permanently implanted catheters; permanently implanted hydrocephalus devices and their implanted pressure regulating components; implanted defibrillators and implanted leads; pacemakers; tendon implants; testicular gel implants; and ear implants.”

The proposed amendments would amend regulation 1591(b)(2) to clarify that tax does not apply to the sale of *all* “permanently implanted articles” including an implant’s interdependent internal and external components, which operate together as one device, in and on the person in whom the device is implanted (including ear implants), unless the device is excluded from the definition of “medicines.”

COST TO LOCAL AGENCIES AND SCHOOL DISTRICTS

The State Board of Equalization has determined that the proposed amendments do not impose a mandate on local agencies or school districts. Further, the Board has determined that the amendments and regulations will result in no direct or indirect cost or savings to any State agency, any costs to local agencies or school districts that are required to be reimbursed under Part 7 (commencing with section 17500) of Division 4 of Title 2 of the Government Code or other non-discretionary costs or savings imposed on local agencies, or cost or savings in federal funding to the State of California.

EFFECT ON BUSINESS

Pursuant to Government Code section 11346.5, subdivision (a)(8), the Board of Equalization makes an initial determination that the adoption of the amendments to Regulation 1591 will have no significant statewide adverse economic impact directly affecting business.

The adoption of the proposed amendments to these regulations will neither create nor eliminate jobs in the State of California nor result in the elimination of existing businesses nor create or expand business in the State of California.

The amendments to the regulations as proposed will not be detrimental to California businesses in competing with businesses in other states.

The proposed regulations may affect small business.

COST IMPACT ON PRIVATE PERSON OR BUSINESSES

The Board is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

SIGNIFICANT EFFECT ON HOUSING COSTS

No significant effect.

FEDERAL REGULATIONS

Regulations 1591 and the proposed changes have no comparable federal regulations.

AUTHORITY

Section 7051, Revenue and Taxation Code.

REFERENCE

Section 6369, Revenue and Taxation Code.

CONTACT

Questions regarding the substance of the proposed regulation should be directed to Mr. Cary Huxsoll (916) 324-2641, at 450 N Street, Sacramento, CA 95814, e-mail Cary.Huxsoll@boe.ca.gov or MIC:82, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0082.

Written comments for the Board's consideration, notice of intent to present testimony or witnesses at the public hearing, and inquiries concerning the proposed administrative action should be directed to Mr. Rick Bennion, Regulations Coordinator, telephone (916) 445-2130, fax (916) 324-3984 , e-mail Richard.Bennion@boe.ca.gov or by mail at State Board of Equalization, Attn: Rick Bennion MIC:81, P.O. Box 942879, 450 N Street, Sacramento, CA 94279-0080.

ALTERNATIVES CONSIDERED

The Board determined that no reasonable alternative considered by it or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which this action is proposed or would be as effective as and less burdensome to affected private persons than the proposed action.

AVAILABILITY OF INITIAL STATEMENT OF REASONS AND TEXT OF PROPOSED REGULATION

The Board has prepared an initial statement of reasons and an underscored and strikeout version (express terms) of the proposed regulation. Both of these documents and all information on which the proposal is based are available to the public upon request. The Rulemaking file is available for public inspection at 450 N Street, Sacramento, California. The express terms of the proposed regulation are available on the Internet at the Board's Web site <http://www.boe.ca.gov>.

AVAILABILITY OF FINAL STATEMENT OF REASONS

The final statement of reasons will be made available on the Internet at the Board's Web site following its public hearing of the proposed regulation. It will also be available for public inspection at 450 N Street, Sacramento, California.

ADDITIONAL COMMENTS

Following the hearing, the State Board of Equalization may, in accordance with the law, adopt the proposed regulations if the text remains substantially the same as described in the text originally made available to the public. If the State Board of Equalization makes modifications which are substantially related to the originally proposed text, the Board will make the modified text, with the changes clearly indicated, available to the public for fifteen days before adoption of the regulation. The text of any modified regulation will be mailed to those interested parties who commented on the proposed regulatory action orally or in writing or who asked to be informed of such changes. The modified regulation will be available to the public from Mr. Bennion. The State Board of Equalization will consider written comments on the modified regulation for fifteen days after the date on which the modified regulation is made available to the public.